

Laparoscopic Sleeve Gastrectomy Versus Laparoscopic Adjustable Gastric Banding for the Treatment Severe Obesity in High Risk Patients

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ABSTRACT

Background: Laparoscopic sleeve gastrectomy (LSG) has emerged as an alternative restrictive bariatric procedure to the most popular laparoscopic adjustable gastric banding (LAGB). We analyze and compare the clinical and weight loss outcomes of LSG versus LAGB for the treatment of severe obesity in high-risk patients.

Methods: Forty severely obese veterans (20/group) received either LSG or LAGB and were followed prospectively for 2 years. Outcome measures included operating room (OR) time, estimated blood loss (EBL), length of hospital stay (LOS), morbidity, mortality, reoperations, readmission rates, and weight loss over time.

Results: The cohort primarily comprised high-risk and older male veterans. Patient's baseline demographics were similar between groups. LSG was associated with prolonged OR time (116 ± 31 vs. 94 ± 28 min), higher EBL (34 ± 28 vs. 17 ± 19 mL), and LOS ($2 \pm .9$ vs. $1 \pm .4$ days) when compared with LAGB. Minor morbidity and readmissions were similar between groups, while no major morbidity, reoperations, or mortality occurred. Total weight and BMI decreased significantly after surgery in both groups (LSG: 302 ± 52 to 237 lbs and 45 ± 5 to 36 ± 5 kg/m² vs. LAGB: 280 ± 36 to 231 ± 29 lbs and 43 ± 5 to 36 ± 5 kg/m², respectively). Total weight loss was superior in the LSG vs. LAGB group at 2 years (TWL = 65 ± 24 vs. 49 ± 28 lbs ($P = .03$); %EWL = 51 ± 20

vs. 46 ± 23 %; %EBMI loss = 48 ± 22 vs. 45 ± 23 %, and %BWL = 21 ± 8 vs. 17 ± 9 %, respectively).

Conclusion: In severely obese and high-risk patients, laparoscopic sleeve gastrectomy provides superior total weight loss at 2 years.

Key Words: Laparoscopic sleeve gastrectomy, Laparoscopic adjustable gastric banding, Severe obesity, Outcomes, Weight loss.

INTRODUCTION

Bariatric surgery is the only effective long-term treatment available for severe obesity that effectively decreases both morbidity and mortality.¹ Roux-Y gastric bypass has been performed for decades, and is the most common bariatric procedure performed in the United States today. However, Roux-Y gastric bypass has been associated with multiple long-term complications. Most recently, restrictive only procedures, such as laparoscopic adjustable gastric banding, have been developed and appear to be related to lower morbidity and mortality. The long-term outcomes associated with the gastric banding procedure have been dissatisfying. Nevertheless, its safety profile has been shown to be better than that of Roux-Y gastric bypass.^{2,3}

Laparoscopic sleeve gastrectomy is a modification of the Magenstrasse and Mill operation that has emerged as an alternative restrictive bariatric procedure to the most popular laparoscopic adjustable gastric banding. Laparoscopic sleeve gastrectomy has not been widely accepted by the Center for Medicare & Medicaid Service (CMS) and few insurance carriers. Therefore, US trials involving this procedure are limited and yet to be published.

The purpose of this clinical trial was to prospectively analyze and compare the perioperative clinical and weight loss outcomes of laparoscopic sleeve gastrectomy vs. laparoscopic adjustable gastric banding for the treatment of severe obesity in high-risk patients.

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MATERIALS AND METHODS

Study Design

A single-institution, prospective equivalency clinical trial was conducted. Patients recruited to participate in this clinical trial underwent surgical procedures and were followed up at the Dallas Veterans Affairs Bariatric Surgery Program for a mean of 2 years. This study was granted Institutional Review Board approval and was registered with the NIH with identifier NCT00434655. Written informed consent was obtained at the time of the first encounter. The purpose of this clinical trial was to compare the short-term clinical and weight loss outcomes of 2 restrictive bariatric procedures, laparoscopic sleeve gastrectomy and laparoscopic adjustable gastric banding, for the treatment of severe obesity. We hypothesized that laparoscopic sleeve gastrectomy provides comparable short-term (2-year) clinical and weight loss outcomes to those of laparoscopic adjustable gastric banding for the treatment of severe obesity in high-risk patients. We specifically aimed to establish differences in perioperative clinical outcomes between groups and to establish differences in weight loss over time between treatment groups. Patient's inclusion and exclusion study entry criteria are shown in **Table 1**. Participating subjects underwent bariatric surgery over a span of an 18-month period as described below. Bariatric surgeons with expertise in both procedures performed the surgical procedures.

Treatment Groups

Laparoscopic Sleeve Gastrectomy

Laparoscopic sleeve gastrectomy was performed by a 5-port approach. The gastrocolic ligament was divided with bipolar cautery (LigaSure Vessel Sealing System, Valleylab, Boulder, CO). The greater curvature of the stomach and the fundus were mobilized. A 32-French blunt bougie was placed transorally and advanced to the pylorus. The sleeve gastrectomy was created by multiple applications of a 60-mm stapler with 4.1-mm staple loads (Echelon 60 Endopath Stapler and Cutter, Ethicon Endo-Surgery, Cincinnati, OH) and staple-line reinforcement (Seamguard, Bioabsorbable Staple Line Reinforcement, W.L Gore and Associate Inc. Flagstaff, AZ), which extended approximately 6cm to 7cm from the pylorus toward the angle of His, creating a gastric tube with approximately 40cc to 50cc of volume. An intraoperative gastroscopy was performed to evaluate the integrity of the staple line and to perform an air leak test. The stomach specimen was extracted through an extended left upper quadrant trocar site.

Laparoscopic Adjustable Gastric Banding

Laparoscopic adjustable gastric banding was performed with 5 abdominal ports. A retro-gastric window was created bluntly by the standard "pars flaccida" technique. A 10-mL AP Standard (APS) LapBand (Allergan Inc, Irvine, CA) was primed on the back table with approximately 3mL of saline solution and inserted into the abdomen, placed below the gastroesophageal junction and buckled

Table 1.
Study Patient Selection Criteria

Inclusion criteria:

1. Adult (>18 y/o) severely obese patients who meet 1991 NIH consensus criteria for obesity surgery (ie, BMI>35 with comorbidities or BMI>40mg/kg²).
2. Patients who have given written informed consent for the study. Their chosen procedure was included in 1 of 2 study groups.

Exclusion criteria:

1. Patients who have contraindications prohibiting general anesthesia.
2. Pregnancy.
3. Previous bariatric, gastric, or upper abdominal procedures, except cholecystectomy.
4. Uncontrollable medical conditions.
5. Uncontrollable psychiatric conditions.
6. Presence of a known large ventral or hiatal hernia.
7. Elderly >65 y/o.

in place. Three anterior nonabsorbable interrupted gastrogastic stitches were placed to secure the band in place. The band tubing was exited and connected to the access port. Saline solution was allowed to exit the tubing until the intraband pressure was equalized with the atmospheric pressure. After this, the access port was implanted subcutaneously and secured to the rectus abdominis fascia with interrupted and nonabsorbable sutures.

Patient Care and Follow-up

Patients underwent routine postoperative care in the post-anesthesia care unit (PACU) and transferred to the surgery ward. A Gastrografin upper gastrointestinal contrast study was obtained on postoperative day # 1 in all patients. Liquid diet was initiated after a normal contrast study was confirmed. Patients were discharged home after they demonstrated that they were ambulatory, tolerating a liquid diet, and achieving incisional pain control with oral narcotics. All participating subjects were followed up 2 weeks after surgery and subsequently on a monthly basis for the first 12 months and every 3 months thereafter for the duration of the study. For the gastric banding group, adjustment sequence was performed at the office until adequate gastric band restriction or the "green zone" was achieved (ie, adequate weight loss, food portion control, minimal postprandial appetite, no reflux, or dysphagia symptoms, and patient's satisfaction) by adding between 1mL and 4mL of saline solution.

Outcome Measures

The main outcome measure for this trial was mean total weight loss (TWL) over time. Weight loss was also expressed as the percentage of excess weight loss (%EWL), percentage of excess of body mass index (BMI) loss (%EBMIL), and percentage of the initial body weight loss (%BWL) over time. The percentage of EWL was calculated as the ratio between excess weight over the ideal body weight (IBW) and postoperative TWL. BMI was estimated as the ratio between weight and height squared. The IBW was obtained according to the published medium size data from the Metropolitan Life Tables. Secondary outcome measures included mean operative time, estimated blood loss, length of hospital stay (LOS), hospital readmissions, reoperation rates, minor and major morbidity, and mortality. Minor morbidity was defined as that one not requiring reoperation or any other invasive or endoscopic intervention or extensive hospital resource utilization. Major morbidity was defined as the one requiring any of the above interventions. Operative time was ob-

tained from the time of the first skin incision until the last wound was closed.

Power Analysis

A total of 40 subjects were required for this equivalency clinical trial (20 per group). An equivalence test of weight loss means using 2 one-sided tests on data from a parallel-group design with sample sizes of 20 in the gastric banding group and 20 in the sleeve gastrectomy group achieved 84% power ($\beta=0.16$) at a 5% significance level when the true difference between the weight loss means is 0.00, the standard deviation is 10.00, and the equivalence weight loss limits are -10.00 and 10.00 lbs. Power analysis was performed using 2008 PASS software (NCSS, Kaysville, UT).

Statistical Analysis

Demographic, clinical, weight loss, and quality of life data were recorded and stored in a secured prospectively collected bariatric surgery database. Outcome data were compared between groups. Differences between group means were determined by 2-sample Student *t* test. Differences between group proportions were established by 2-sample Z-test. A P-value <.05 was considered statistically significant. Statistical analysis was performed with the 12.0 SPSS statistical software (SPSS, Chicago, IL).

RESULTS

Demographic Data

Mean age, sex, and race/ethnicity distributions were comparable between bariatric surgery groups (**Table 2**). Pre-operative mean height, weight, and BMI were similar in both groups. There were no differences in American Society of Anesthesiologists (ASA) scores. The majority of patients fell in the high-risk category: ASA scores ≥ 3 , mean age ≥ 50 years, and male sex.

Clinical Outcome Data

In the sleeve gastrectomy group, the mean operative room time and estimated blood loss were significantly higher compared to that with gastric banding. The sleeve gastrectomy group's length of hospital stay doubled that of gastric banding. Minor morbidity was similar between procedures (**Table 3**). There were no major complications, mortality, or reoperations in either group. Readmissions were similar between treatments (one in each arm).

Morbidity Data

Overall morbidity and procedure-related complications were comparable between groups (**Table 4**). Morbidity in the gastric banding group was related to an overfilled band causing postoperative food intolerance that resolved with band deflation. One sleeve gastrectomy patient was readmitted for intravenous hydration due to poor oral intake and dehydration. A second sleeve gastrectomy patient developed tape allergy with blistering that resolved with local therapy, and a third patient had postoperative uncontrolled diabetes that required intravenous insulin therapy in the ICU. There was one wound cellulitis epi-

sode in each group that did not require wound reopening and resolved with oral antibiotics.

Weight Loss Data

Total weight and BMI decreased significantly after surgery in both groups at 2 years (LSG: 302 ± 52 to 237 lb and 45 ± 5 to $36 \pm 5 \text{ kg/m}^2$ vs. LAGB: 280 ± 36 to $231 \pm 29 \text{ lb}$ and 43 ± 5 to $36 \pm 5 \text{ kg/m}^2$, respectively; **Table 5**). Weight loss was equivalent at 12 months: $\text{TWL} = 67 \pm 24$ vs. $52 \pm 28 \text{ lb}$; $\% \text{EWL} = 52 \pm 20$ vs. $47 \pm 23\%$; $\% \text{EBMI loss} = 49 \pm 22$ vs. $46 \pm 23\%$ and $\% \text{BWL} = 22 \pm 8$ vs. $19 \pm 9\%$, respectively. However, total weight loss was superior in the LSG group at 24 months ($\text{TWL} = 65 \pm 24$ vs. $49 \pm 28 \text{ lb}$ ($P = 0.03$); $\% \text{EWL} = 51 \pm 20$ vs. $46 \pm 23\%$; $\% \text{EBMI loss} = 48 \pm 22$ vs. $45 \pm 23\%$ and $\% \text{BWL} = 21 \pm 8$ vs. $17 \pm 9\%$, respectively).

DISCUSSION

In the present severely obese and high-risk cohort, we demonstrated that laparoscopic adjustable gastric banding

Table 2.
Preoperative Patient's Characteristics

Variables ^a	LSG ^a	LAGB ^a
Mean age (years)	51.7 ± 8	54.9 ± 8
Male sex (%)	60.0	80.0
Race/ethnicity (%)		
Caucasians	75.0	60.0
Blacks	15.0	35.0
Hispanics	10.0	5.0
Mean height (inches)	68.8 ± 4	68.5 ± 3
Mean weight (lb)	302 ± 52	280 ± 36
Mean ideal body weight (lb)	218 ± 39	213 ± 26
Mean BMI (kg/m^2)	44.8 ± 5	42.5 ± 5
ASA score ≥ 3 (%)	75	75

^aBMI=body mass index; ASA=American Society of Anesthesiologists; LSG=laparoscopic sleeve gastrectomy; LAGB=laparoscopic adjustable gastric band.

Table 3.
Perioperative Clinical Outcomes Data

Variables ^a	LSG ^a (mean \pm SD)	LAGB ^a (mean \pm SD)
OR time (minutes)	115.6 ± 31	93.9 ± 28^b
EBL (mL)	33.8 ± 28	16.6 ± 19^b
ICU utilization (%)	35.0	25.0
Mean LOS (days)	$2.4 \pm .9$	$1.2 \pm .4^b$
Overall morbidity (%)	20.0	10.0
Mortality (%)	0	0

^aLSG=laparoscopic sleeve gastrectomy; LAGB=Laparoscopic adjustable gastric band; EBL=estimated blood loss; ICU=intensive care unit; LOS=length of stay.

^b $P < .05$ vs. LSG by *t* test.

Table 4.
Short-term Morbidity Data

Variable	LSG ^a	LAGB ^a
Minor Morbidity (%)	20.0	10.0
— Wound cellulitis	5.0	5.0
— Tape allergy	5.0	0
— Nausea/vomiting	5.0	5.0
— Uncontrolled DM ^a	5.0	0
Major Morbidity	0	0
Readmissions	5.0	5.0
Reoperations	0	0

^aDM=Diabetes Mellitus; LSG=laparoscopic sleeve gastrectomy; LAGB=laparoscopic adjustable gastric band.

Table 5.
Two-year Weight Loss Data

Weight Loss ^a	LSG ^a (Mean \pm SD)	LAGB ^a (Mean \pm SD)
TWL (lb)	65 ± 24	$49 \pm 28^*$
EWL (%)	51 ± 20	46 ± 23
EBMI (%)	48 ± 22	45 ± 23
BWL (%)	21 ± 8	17 ± 9

^aLSG=laparoscopic sleeve gastrectomy; LAGB=laparoscopic adjustable gastric band; TWL=total weight loss; EWL=excess weight loss; EBMI=excess of body mass index loss; BWL=initial body-weight lost.

and laparoscopic sleeve gastrectomy are both safe and effective procedures for the treatment of severe obesity. Both approaches are associated with low short-term morbidity and readmission rates with no reoperations or mortality. However, laparoscopic sleeve gastrectomy provides superior total weight loss at 2 years.

Prospective randomized trials have shown favorable outcomes with the use of laparoscopic over open bariatric surgical techniques.^{4–7} Therefore, bariatric surgery has shifted to predominantly laparoscopic approaches. In the US, the most common laparoscopic bariatric surgery has been Roux-Y gastric bypass. Unfortunately, this procedure has been associated with various long-term complications and may not be most suitable for high-risk and older populations.

In a recent perioperative safety longitudinal bariatric surgery study, bariatric surgery was found to be a very safe procedure with mortality rates close to those of hip replacement or cholecystectomy.⁸ This large cohort study showed that severely obese patients who underwent laparoscopic gastric bypass had a higher risk of adverse events compared to those who underwent laparoscopic adjustable gastric banding.

Laparoscopic restrictive procedures, particularly adjustable gastric banding, has been shown to have an improved safety profile compared to gastric bypass.^{2,3} Therefore, this restrictive only procedure became very popular after its FDA approval in 2001. Most recently, laparoscopic sleeve gastrectomy emerged as an alternative primary procedure to the popular gastric banding for the treatment of severe obesity. Sleeve gastrectomy is currently not widely available, because it has not been approved as a covered benefit by the CMS. Its implementation is limited to select high-risk individuals and bariatric centers as a first stage of a 2-staged procedure.⁹ This translates into lack of evidence-based data where the number of US trials is insufficient. Not long ago, the American Association of Metabolic and Bariatric Surgery released a revised statement identifying laparoscopic sleeve gastrectomy as a suitable option for select severely obese individuals.¹⁰ There also has been concern among bariatric surgeons regarding the sleeve gastrectomy safety profile and sustained weight loss over time.

Although, laparoscopic gastric banding and sleeve gastrectomy are both considered restrictive operations, surgical techniques, postoperative care, and weight loss mechanistic pathways vary widely. In addition, sleeve gastrectomy is perceived as a more invasive procedure because at least two-thirds of the stomach is removed.

Gastric banding produces adjustable restriction to food and appetite reduction by unclear mechanisms, while sleeve gastrectomy induces weight loss by ghrelin elimination, rapid gastric emptying, and other unknown hormonal mediated mechanisms with almost complete appetite suppression.¹¹ Compared to the gold standard operation, laparoscopic Roux-Y gastric bypass, both laparoscopic restrictive procedures are indeed less complex and demanding.

There is a substantial number of severely obese among veterans being cared for at the Veterans Affairs Health Care System (VAHCS).¹² The VAHCS has the highest rate of severe obesity of any other health care system, with 37% of females and 33% of males being obese. This high prevalence has increased the number of bariatric surgeries within the VAHCS. The VAHCS severely obese veterans who undergo bariatric surgery differ from those at academic or private sectors, which comprise mostly younger and low-risk females. Veterans are predominantly older males with severe systemic diseases and lower socioeconomic background.¹³ Both laparoscopic gastric banding and sleeve gastrectomy procedures appear to be tailored to this severely obese and high-risk veteran population.

Our data support findings of prospective randomized clinical trials by Himpens et al¹⁴ comparing gastric banding and sleeve gastrectomy, where weight loss was superior for the sleeve group however with a higher number of complications. Sleeve gastrectomy has also been shown to provide more than 50% of excess weight loss at 6 years.¹⁵ In our study, the total weight loss was greater after sleeve gastrectomy at 2 years. In addition, there was a general trend that favored laparoscopic sleeve gastrectomy in other weight loss parameters. No significant weight loss differences between the first and second year was observed. This may be likely to an increase in follow-up visit intervals during the second year. The majority of weight loss occurred within the first year and stabilized at year 2 with no additional weight loss. The weight loss of the sleeve gastrectomy and gastric banding groups are similar to those reported in other studies. These data suggest that close follow-up may also be essential for sleeve gastrectomy patients, to prevent weight regain or weight loss failure.

The complication rates between gastric banding and sleeve gastrectomy groups did not reach statistical significance in the present study. What is evident is that when complications occurred, they did not require additional invasive procedures or extensive hospital resource utilization. On the other hand, no major complications or

reoperations were required during the study period. The hospital length of stay for the sleeve gastrectomy group was twice that of the gastric banding group. This was commonly the result of increased incisional pain at the sleeve specimen extraction site. Operative times observed with sleeve gastrectomy were prolonged compared to operative times for banding. The increased time in this group was likely associated with additional procedural steps including gastroscopy, leak testing, and specimen extraction. Finally, the intraoperative blood loss with gastric banding was significantly lower but perhaps this finding is of no clinical relevance.

This study has several limitations. First, this trial was not randomized. It proved difficult to randomize subjects to 2 very dissimilar surgical procedures at a medium volume bariatric program. Second, we analyzed short-term outcomes only, and follow-up was insufficient to provide long-term (> 2 years) weight loss comparisons. Lastly, the study did not provide enough power to allow comparisons of resolution of comorbidities.

CONCLUSION

In the context of this severely obese, high-risk, older male cohort, laparoscopic sleeve gastrectomy was associated with prolonged operative time, blood loss, and hospital stay compared with laparoscopic adjustable gastric banding. Both procedures have low short-term minor morbidity and readmission rates with no associated major morbidity, reoperations, or mortality. Both approaches are safe and effective for the treatment of severe obesity. However, laparoscopic sleeve gastrectomy offers superior 2-year total weight loss. Long-term prospective randomized trials comparing both surgical treatments in large groups of severely obese and high-risk patients are warranted.

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